

1 METHOD OF APPLYING SURGICAL CLIPS TO TISSUE

2

3 This application is a continuation-in-part of U.S. Serial No.
4 09/891,775, filed June 25, 2001, which is hereby incorporated by
5 reference herein in its entirety.

6

7

BACKGROUND OF THE INVENTION

8

9 1. Field of the Invention

10 This invention relates broadly to methods of using surgical
11 devices. In particular, this invention relates to a method of
12 using a surgical clip applier to apply a surgical clip over tissue
13 and to deform the clip to enhance retention.

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1 2. State of the Art

2 Surgical clips are generally used to apply clamping force to
3 ducts, vessels, and other tissues. In addition, surgical clips
4 are particularly useful in controlling bleeding of a tissue in
5 lieu of suturing or stapling where suturing or stapling is
6 difficult.

7
8 All of the currently available surgical multifiring clip
9 applicators are substantially rigid devices intended to extend
10 through a trocar port or through an incision to a surgical site
11 requiring application of a clip. The devices have been rigid
12 because a stiff pushing element has been required in order to
13 exert the required pushing force to move the clip over the tissue.

14
15 However, there is a substantial need for a flexible clip
16 applicator, particularly one insertable through a lumen of an
17 endoscope. The ability to apply clips through an endoscope would
18 permit myriad minimally invasive surgical solutions to medical
19 problems, especially those of the gastrointestinal tract.
20 However, it is accepted theory that the transmitted force required
21 to advance or form a clip over tissue cannot be produced in the
22 distalmost end of a long flexible device that is commonly
23 constructed with a metal tubular coil, or polymer tube, such as an
24 endoscopic device or catheter. For example, C. Paul Swain, MD, a
25 recognized expert in endoscopic instruments and particularly

1 endoscopic stapling devices, has stated that "[i]t is hard to
2 exert more than 200g of force on the tissue when pushing
3 This fact is of course one feature that makes intervention at
4 flexible endoscopy relatively safe". See C. Paul Swain, "What
5 Endoscopic Accessories Do We Really Need?", *Emerging Technologies*
6 *in Gastrointestinal Endoscopy, Gastrointest. Endosc.*, Vol. 7, No.
7 2, pp. 313-330 (April 1997). Yet, a pushing force substantially
8 greater than 200g is required to push a clip over compressed
9 tissue. In fact, it is believed a force in excess of 500 grams
10 (1.1 lbs) is required for a satisfactory instrument, and
11 substantially greater forces, e.g., in excess of 1500 grams (3.3
12 lbs) would be desirable.

13
14 Generally a flexible endoscopic device (e.g., a biopsy
15 forceps device) includes an outer tubular member, typically being
16 constructed of a metal tubular coil or a polymer tube which is
17 poor in transmitting forces that impart tensile stresses to the
18 outer sheath, a control element longitudinally movable relative to
19 the tubular member, an end effector coupled to the distal ends of
20 both the tubular member and the control element such that relative
21 movement of the control element and the tubular member causes
22 operation of the end effector, and a handle which moves the
23 control element relative to the handle. This type of flexible
24 endoscopic instrument is limited in the amount of pushing force it
25 can generate for several reasons. Compression of a flexible

1 control element (pushing element) tends to cause the pushing
2 element to buckle within the outer flexible sheath of the device.
3 If a relatively larger diameter flexible pushing element is used
4 such that it better resists buckling, the pushing element may
5 impart too much stiffness to the flexing of the endoscopic
6 instrument. In addition, a flexible pushing element of larger
7 diameter is subject to greater frictional forces within the outer
8 sheath which reduces the force transmitted from the handle to the
9 end effector. If the flexible pushing element is made relatively
10 smaller in diameter, it is subject to kinking which will result in
11 little to no force transmitted to the distal end. Kinking is
12 especially a problem in endoscopic instruments, as the endoscope
13 and its lumen may be extended through a tortuous path. For these
14 reasons and others, mechanical application of a relatively large
15 distal end pushing force and particularly clip application have
16 been absent from the capability of flexible endoscopic tools.

17 18 SUMMARY OF THE INVENTION

19
20 It is therefore an object of the invention to provide a
21 flexible endoscopic device capable of generating a relatively
22 large pushing force at its distal end.

23
24 It is another object of the invention to provide an
25 endoscopic clip applier.

1 It is a further object of the invention to provide a flexible
2 clip applier which can exert a pushing force of at least 500 grams
3 (1.1 lbs), and preferably in excess of 1500 grams (3.3 lbs) via a
4 manually actuatable handle.

5
6 It is an additional object of the invention to provide a
7 surgical clip applier which is adapted for use in minimally
8 invasive surgery.

9
10 It is also an object of the invention to provide a surgical
11 clip applier which has a pushing element which is not subject to
12 kinking.

13
14 It is yet another object of the invention to provide a
15 surgical clip applier which has a pushing element which does not
16 create unsuitably high frictional forces within the outer sheath.

17
18 It is still a further object of the invention to provide a
19 surgical clip applier which can store and apply multiple clips.

20
21 In accord with these objects, which will be discussed in
22 detail below, a surgical clip applier is provided having a
23 flexible, preferably flat wire wound outer tubular coil, a pair of
24 jaws at the distal end of the tubular coil, a set of end effector
25 wires extending through the outer tubular coil and coupled to the

1 jaws, and a clip-advancing wire extending through the tubular
2 coil. A lubricious, preferably extruded polymer, multilumen
3 barrier sheath extends within the tubular coil and separates the
4 wires from each other and the tubular coil. A clip chamber is
5 provided in the distal end of the tubular coil and stores a
6 plurality of linearly arranged clips. A clip pusher is provided
7 at a distal end of the clip-advancing wire, and adapted to advance
8 the clips in the chamber toward the jaws when the clip-advancing
9 wire is advanced through the barrier sheath and outer tubular
10 coil. The jaws include clamping surfaces which operate to
11 compress tissue between the jaws when the jaws are closed, guides
12 in which a distalmost clip rides distally and is advanced over the
13 clamped tissue when the line of clips is advanced by the clip
14 pusher, and a distal anvil which operates to bend a portion of the
15 distalmost clip to enhance its retention on the clamped tissue. A
16 proximal handle is provided for movement of the clip-advancing
17 wire and end effector wires relative to the barrier sheath to
18 effect (1) clamping and rotation of the jaws (relative to each
19 other and about the longitudinal axis of the tubular coil), and
20 (2) advancement of the clip-advancing wire to effect distal
21 movement of a clip.

22
23 The flat wire wound tubular coil is preferred over round wire
24 (though not necessarily required over a round wire wound tubular
25 coil) because it is flexible, yet sufficiently longitudinally

1 stiff such that the device may be pushed through the lumen of the
2 endoscope. In addition, the flat wire wound tubular coil can be
3 made with a high preload and has a tensile spring constant
4 sufficiently high that it resists buckling and uncoiling during
5 application of a pushing force by the handle against the clip-
6 advancing wire. The clip-advancing wire has a sufficiently large
7 diameter to transmit force, yet small enough to minimize internal
8 friction when moved within a device flexed through a tortuous path
9 in an endoscope. The end effector wires are large enough to
10 handle the high closing force from the handle, and to resist
11 compressive buckling when moved in an opposite direction, yet
12 small enough to be coupled to diminutive jaws. The multilumen
13 barrier sheath supports the clip-advancing wire and end effector
14 wires along their length to reduce compressive buckling, and
15 provides a separation layer to reduce friction. Movement of the
16 clip-advancing wire relative to the outer tubular coil causes a
17 compressive force in the clip-advancing wire and tensile forces in
18 the outer tubular member such that a relative pushing force is
19 transmitted to the distal end of the clip-advancing wire in excess
20 of the perceived threshold of the 200 grams (0.44 lbs). In fact,
21 one embodiment of the device of the invention, sized for
22 endoscopic use, provides a pushing force in excess of 2267 grams
23 (5 lbs).

24

1 In operation, the jaws can be moved through a working channel
2 of an endoscope in a closed position. Once exited, the handle can
3 be operated to open the jaws and rotate the jaws to a desired
4 orientation. The jaws are positioned on either side of tissue
5 about which it is desired to place a clip and the handle is
6 operated to pull the end effector wires such that the jaws clamp
7 about the tissue. The handle is then locked to maintain the jaws
8 in the clamped position. The handle is operated to effect
9 advancement of the clip-advancing wire through the tubular coil
10 such that a clip is advanced through the jaw guides and over the
11 tissue. The clip is advanced until a portion thereof is forced
12 against the anvil of the jaws to effect bending of the clip
13 portion such that that portion moves laterally to pierce the
14 clamped tissue. After the clip is applied, the jaws are released
15 from about the tissue, and the end effector assembly may then be
16 moved to another tissue location to apply additional clips.

17
18 Additional objects and advantages of the invention will
19 become apparent to those skilled in the art upon reference to the
20 detailed description taken in conjunction with the provided
21 figures.

22

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a partial section side elevation view of a surgical clip applier according to the invention, shown with the handle configured to provide the jaws in an open configuration;

Fig. 2 is a broken perspective view of a distal portion of the clip applier according to the invention;

Fig. 2A is an exploded and broken perspective view of a distal portion of the clip applier according to the invention;

Fig. 2B is a broken schematic view of a distal end of the clip-advancing wire and the coil connector;

Fig. 2C is a broken schematic view of a distal end of the clip-advancing wire and the coil connector illustrating the limitation on proximal movement of the clip-advancing wire relative to the coil connector;

Fig. 3 is a perspective view of the jaw assembly of the clip applier according to the invention, and a clip;

Fig. 4 is a partial section side elevation view of a surgical clip applier according to the invention, showing the right side of

1 the handle positioned to place the jaws in an unloaded closed
2 configuration;

3

4 Fig. 4A is a view similar to Fig. 4, illustrating alternative
5 embodiments to the handle of the clip applier according to the
6 invention;

7

8 Fig. 5 is an enlarged view of the handle of the surgical clip
9 applier with the handle in the same position as shown in Fig. 4;

10

11 Fig. 6 is a view similar to Fig. 4 of the left side of the
12 handle;

13

14 Fig. 7 is a view similar to Fig. 6 with the addition of the
15 various springs;

16

17 Fig. 8 is an enlarged broken section view of the proximal
18 left side of the handle of the clip applier according to the
19 invention;

20

21 Fig. 9 is an enlarged side perspective view of the end
22 effector assembly;

23

24 Fig. 10 is an enlarged distal end perspective view of the end
25 effector assembly;

1 Fig. 11 is a broken partial section side elevation view of
2 the distal end of the clip applier according to the invention;
3

4 Fig. 12 is a view similar to Fig. 1, showing the handle
5 configured such that the jaws are in a unloaded closed position,
6 and shown without the pinion on the jaw closing lever;
7

8 Fig. 13 is a partial section perspective view of a surgical
9 clip applier according to the invention, illustrating rotation of
10 the end effector assembly by operation of the rotation knob;
11

12 Fig. 14 is a partial section side elevation view of a
13 surgical clip applier according to the invention, showing the jaws
14 in a clamped configuration;
15

16 Fig. 15 is a partial section side elevation view of a
17 surgical clip applier according to the invention, showing the jaws
18 in a clamped configuration and the clip-advancing lever actuated;
19

20 Fig. 16 is an enlarged partial section view of the handle of
21 the surgical clip applier, showing the clip-advancing lever
22 actuated;
23

1 Fig. 17 is a longitudinal section view of the distal end of
2 the clip applier according to the invention, shown with the jaws
3 in a closed configuration and a formed clip therebetween;
4

5 Fig. 18 is a broken partial section side elevation view of
6 the distal end of the clip applier according to the invention,
7 shown with the jaws in an open configuration and a formed clip
8 therebetween;
9

10 Fig. 19 is a broken partial section side elevation view of
11 the distal end of the clip applier according to the invention,
12 shown with the jaws in an open configuration, the formed clip
13 released, and the retainer of a subsequent clip protruding between
14 the jaws;
15

16 Fig. 20 is a longitudinal section view of the distal end of
17 the clip applier according to the invention, shown with the jaws
18 in an open configuration and the retainer retracted relative to
19 the view of Fig. 19;
20

21 Fig. 21 is a partial section side elevation view of a
22 surgical clip applier according to the invention, shown with the
23 jaws in an open position and a formed clip released therefrom;
24

1 Fig. 22 is a table listing dimensions for the tubular coil,
2 clip-advancing wire, and end effector wires of six prototypes, and
3 the resultant output force achieved with the prototype; and
4

5 Fig. 23 is an efficiency plot of the prototypes described in
6 the table of Fig. 22.
7

8 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

9
10 Turning now to Figs. 1, 2, 2A and 3, a flexible clip applicator
11 suitable for insertion through a working channel (lumen) of an
12 endoscope is shown. The clip applicator 10 generally includes a
13 flexible, flat wire wound outer tubular coil 12 having an end
14 effector assembly 13 mounted at a distal end 16 thereof. The end
15 effector assembly 13 includes a clevis (jaw mount) 14 rotatably
16 supporting a pair of jaws 18, 20. End effector wires 22, 24
17 extend through the tubular coil 12 and have distal ends 26
18 respectively coupled to the jaws 18, 20. A clip-advancing wire 30
19 extends through the tubular coil 12 and includes a distal end 32
20 provided with a clip pusher 34. A lubricious, preferably
21 extruded, multilumen barrier sheath 36 extends through
22 substantially the entire length of the outer tubular coil 12 and
23 separates the end effector wires 22, 24 and clip-advancing wire 30
24 from each other and the outer tubular coil 12. A proximal handle
25 assembly 40 is provided for moving the end effector wires 22, 24

1 and clip-advancing wire 30 relative to the tubular coil 12 to
2 effect clamping and rotation of the jaws and advancement of a
3 clip, as described in detail below.

4
5 Referring to Figs. 4 and 5, more particularly, the handle
6 assembly 40 includes a housing defined by two shell portions 42,
7 44, a stationary handle 46, a jaw closing lever 48 linearly
8 movable within a slot 50 in the housing and relative to the
9 stationary handle 46, and a clip-advancing lever 52 rotatably
10 mounted on the jaw closing lever 48 with a pivot pin 54. The jaw
11 closing lever 48 is coupled to the end effector wires 22, 24, as
12 described in detail below. The jaw closing lever 48 is biased
13 into an open position (away from the stationary handle 46) with a
14 constant force spring 56 held in a distal portion of the housing
15 such that the jaws 18, 20 are in an open configuration when no
16 manual force is applied against the force of the spring 56 to move
17 the jaw closing lever toward the stationary handle. The clip-
18 advancing lever 52 is forced into an open position, also away from
19 the stationary handle 46, with a torsion spring 58 (Figs. 4 and
20 7). The clip-advancing lever 52 is coupled to the clip-advancing
21 wire 30, as discussed in detail below, with rotation of the clip-
22 advancing lever 52 operating to move the clip pusher 34 at the
23 distal end 32 of the clip-advancing wire 30 longitudinally within
24 the tubular coil.

1 A tube 60 extends from the interior of the handle 40 to the
2 exterior and includes a proximal rotation knob 62. The proximal
3 end of the clip-advancing wire 30 is clamped, or otherwise held,
4 within the tube 60 such that rotation of the knob 62 causes
5 rotation of the entire clip-advancing wire. A distal end 64 of
6 the tube 60 is rotatably coupled within a collar 66. The collar
7 66 is fixedly coupled to a rack 68. Linear movement of the rack
8 68 within the housing causes the tube to move longitudinally
9 within and outside the housing.
10

11 Alternatively, referring to Fig. 4A, the tube 60 may be
12 telescoping, having two rotationally interfering sections 60a and
13 60b, such that movement of the rack 68 moves a distal section 60a
14 of the tube relative to a proximal section 60b, thereby
15 maintaining a constant length for extension of the proximal
16 section 60b of the tube outside the housing. The rotationally
17 interfering portions, e.g., each having a hex shape, permit
18 rotationally forces to be transmitted from the knob 62 to the
19 distal end 64 of the tube.
20

21 Referring back to Fig. 4, a pinion 70 is rotatably mounted at
22 72 to an upper portion 74 of the clip-advancing lever 52 and
23 positioned to act on the rack 68 when the clip-advancing lever is
24 rotated. As such, when the clip-advancing lever 52 is rotated
25 about pivot 54 toward the jaw closing lever 48, the rack 68 and

1 the clip-advancing wire 30 are advanced. The rack 68 is
2 preferably substantially longer than what is required by the
3 number of teeth on the pinion 70. As a result, the pinion 70 can
4 act upon the rack 68 in any location at which the jaw closing
5 lever 48 may be positioned upon closing the jaws 18, 20. This,
6 when the jaw closing lever 48 is pulled back toward the stationary
7 handle 46 to effect closure of the jaws 18, 20 about tissue, the
8 jaw closing lever 48 may be located at a location which is
9 consistent with the thickness and consistency of the tissue about
10 which the jaws are to be closed.

11
12 The teeth of the pinion 70 are preferably at a positive
13 engagement angle relative to the teeth of the rack 68 because of
14 the location of the pinion pivot axis 72. Then, when the pinion
15 is rotated, the rack is moved longitudinally. A leaf spring 76
16 acts between the pinion 70, at hole 78, and the advancing lever 52
17 at shelf 77 to force the pinion 70 into the rack 68. After firing
18 a clip, as discussed below, release of the clip-advancing lever 52
19 allows the spring 58 to return the lever 52 back to its unbiased
20 position, and the pinion 70 rotates about the pinion axis 72
21 against the leaf spring 76 and over the rack 68.

22
23 Turning now to Figs. 6 through 8, the jaw closing lever 48
24 includes a spring activated catch system 80 which locks the jaw
25 closing lever when a predetermined load is applied thereto rather

1 than when the closing lever is located at any particular location.
2 The catch system 80 includes the following structures on an upper
3 mount portion 82 of the jaw closing lever 48: a proximal spring
4 mount 84; two spaced apart bolts 86, 88; and a locking tooth 90.
5 The locking tooth 90 includes a proximal cam 92. The catch system
6 80 further includes the following additional structures: a latch
7 94 having a linear slot 96 and a cam slot 98, which are positioned
8 over bolts 86, 88 respectively; an end effector wire mount 100 to
9 which the proximal ends of the end effector wires 22, 24 are
10 attached; an upper cam surface 102 for the below-described lever
11 lock 110; and a spring catch 104. An extension spring 106 (Fig.
12 7) is held between the spring mount 84 and spring catch 104. A
13 generally L-shaped lever lock 110 is rotatably coupled about a
14 lever pivot 114 formed at the proximal end of the handle. An
15 elongate portion 116 of the lock 110 includes a comb; i.e., the
16 portion 116 includes a plurality of teeth 118, each of which
17 include a distal camming surface 120. Another portion 122 of the
18 lever lock 110 is provided with a release button 124 which extends
19 outside of the handle housing. A torsion spring 130 is provided
20 about the pivot 114 to bias the lever lock 110 down toward the
21 locking tooth 90. A safety 132 is also provided to prevent
22 release of the jaw closing lever 48 when the clip-advancing lever
23 52 is moved from an unbiased position, thereby preventing
24 inadvertent release of unapplied clips.

1 Once the jaws are closed about tissue, as discussed further
2 below, it is desired to maintain their closed position until a
3 clip is advanced over the tissue. In view of this object, the
4 catch system 80 function as follows. Still referring to Figs. 6
5 through 8, the cam surface 102 is generally adapted to position
6 the teeth 118 of the lever lock 110 located in front of the
7 locking tooth 90 above the locking tooth, such that the jaw
8 closing lever 48 may be moved linearly. When the jaw closing
9 lever 48 is moved toward the stationary lever 46, tension is
10 increased in the end effector wires 22, 24 to move the jaws 18, 20
11 from an open position to a closed position. As the tension
12 increases in the end effector wires 22, 24 and exceeds the tension
13 of the extension spring 106, the latch 94 moves distally relative
14 to the jaw closing lever 48. Then, movement of the jaw closing
15 lever 48 relative to the latch 94 causes the bolts 86, 88 to ride
16 within the linear slot 96 and the camming slot 98, respectively.
17 Referring to Fig. 8, movement of bolt 88 within camming slot 98
18 forces the proximal end of the latch 94 downward and permits the
19 lever lock 110 to rotate clockwise. This causes the locking tooth
20 90 to engage the toothed portion 116 of the lever lock 110 and
21 lock the position of the jaw closing lever 48. The load applied
22 to the end effector wires is then limited to the force applied by
23 the extension spring 106 (Fig. 7). The jaw closing lever 48 then
24 may be released by pushing the release button 124 sufficiently to

1 rotate the lever lock 110 against the bias of the torsion spring
2 130 and clear the locking tooth 90.

3
4 Turning now to Figs. 1, 2, 4 and 6, the distal end of the
5 housing 42, 44 of the handle assembly 40 includes a slot 131 in
6 which two preferably substantially rigid and preferably low
7 friction tubes 133, 135, e.g., brass tubes, are provided. The
8 proximal end 136 of the tubular coil 12 is coupled to the housing
9 in alignment with the tubes 133, 135 with a flare nut coupling 138
10 or an equivalent assembly. The clip-advancing wire 30 extends
11 from the rotation tube 60 through tube 133 and into a clip-
12 advancing wire lumen 140 of the barrier sheath 36. The clip-
13 advancing wire 30 extends therethrough to the distal end 16 of the
14 tubular coil 12. The end effector wires 22, 24 extend from end
15 effector wire mount 100 through tube 135 and into respective end
16 effector wire lumina 142, 144 of the barrier sheath 36, and then
17 extend therethrough to the distal end of the tubular coil. Wires
18 22, 24 and 30 are provided in separate lumina within the barrier
19 sheath 36 in order to minimize friction between the wires and
20 reduce buckling and kinking of the wires along the length of the
21 tubular coil 12.

22
23 Turning again to Fig. 4A, rather than using tubes to direct
24 the wires from the housing into the barrier sheath in tubular
25 coil, the housing may be formed with channels which provide the

1 same function. For example, channels 132a, 132b are adapted to
2 direct the clip-advancing wire 30 and end effector wires 22, 24,
3 respectively, into the barrier sheath 36 within the tubular coil
4 12. In addition, the housing may be formed with distal structure,
5 e.g., a cylindrical protrusion 146, facilitating the coupling of a
6 flare nut assembly thereto.

7
8 Referring back to Fig. 2, the tubular coil 12 is a preferably
9 stainless steel (or other metal or metal alloy) flat wire wound
10 wire tubular coil, though a round wire wound tubular coil may be
11 used. The tubular coil 12 is fairly stiff such that the device
12 can be pushed through the endoscope to the treatment area. The
13 tubular coil 12 has a spring constant sufficiently high in order
14 to resist uncoiling when subject to the tensile load created when
15 the handle applies a pushing force to the clip-advancing wire and
16 the clips, as discussed in more detail below, and minimize
17 buckling during force transmission. In addition, the tubular coil
18 12 is preloaded such that each turn is substantially in contact
19 with the adjacent turns 360° around the tubular coil. The outer
20 diameter of the tubular coil 12 has an outer diameter smaller than
21 the inner diameter of the working channel (lumen) of an endoscope
22 for which it is intended, and the inner diameter of the tubular
23 coil should be maximized so that it may readily accept the barrier
24 sheath, and clip-advancing wire and end effector wires, as well as
25 form a chamber for a plurality of clips, as discussed below. In

1 preferred embodiments, the tubular coil 12 of a device adapted for
2 an endoscope having a 3.2 mm working channel has an outer diameter
3 preferably not exceeding approximately 3.175 mm (0.125 inch), and
4 a preferably an inner diameter of at least approximately 0.90 mm
5 (0.035 inch) so that it may accept the end effector wires 22, 24,
6 clip-advancing wire 30, barrier sheath 36, and clips 202. The
7 tubular coil inner diameter preferably corresponds to the
8 transverse dimension of a clip 202, discussed below, so that the
9 clip is stably directed through the chamber 200. The wire of the
10 tubular coil 12 has a width W preferably between approximately
11 0.635 mm to 1.270 mm (0.025 inch to 0.050 inch), and a thickness T
12 preferably at least approximately 0.13 mm to 0.75 mm (0.005 inch
13 to 0.030 inch). The tubular coil length should at least be the
14 length of the endoscope working channel, generally 150 cm to 250
15 cm. A substantial length of the tubular coil 12 is preferably
16 covered in a high density polyethylene (HDPE) sheath 150 (Figs. 1,
17 2 and 2A).

18
19 The barrier sheath 36 within the tubular coil is preferably
20 non-circular in shape to reduce contact points and thereby
21 minimize friction between the barrier sheath and the tubular coil.
22 The primary purpose of the sheath is to maintain a close fitting
23 bearing surface for the clip-advancing wire, although its three
24 distinct lumina help reduce friction between all the wires. The
25 sheath 36 preferably free floats within the tubular coil; i.e., it

1 is not attached to the tubular coil at its ends or along its
2 length. Preferred cross-sectional shapes include generally
3 rectangular and triangular (each with or without broken or rounded
4 edges) and trefoil. The barrier sheath 36 is preferably an
5 extrusion made from polypropylene, an FEP fluoropolymer resin
6 (FEP), polytetrafluoroethylene (PTFE), high density polyethylene
7 (HDPE), nitrol polyvinyl chloride, nylon, or any other lubricious
8 polymer.

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10 The clip-advancing wire 30 is preferably made of nickel-
11 titanium alloy (NiTi) or stainless steel. The NiTi construction
12 permits the clip-advancing wire 30 to transmit torque (by rotation
13 of the rotation knob 62) without taking a cast, and with minimal
14 whipping. The clip-advancing wire 30 has a sufficiently large
15 diameter to transmit force, yet not so large that it is prevented
16 from functioning through a tortuous path or fit within the tubular
17 coil 12. A preferred diameter for the clip-advancing wire is
18 approximately 0.375 mm to 0.89 mm (0.015 inch to 0.035 inch).

20 Referring to Figs. 2, 2A and 2B, the distal end 32 of the
21 clip-advancing wire 30 has a non-circular cross-section, and is
22 preferably rectangular in shape. The distal end 32 is preferably
23 a length four to five times the length of the clip pusher 34. A
24 coil connector 152 is coupled within the distal portion 16 of the
25 tubular coil 12, e.g., by welding, press fitting, interference

1 fit, pinning, etc., preferably approximately 25 mm to 50 mm from
2 the distal end of the tubular coil (i.e., the length of a linear
3 arrangement of five or so clips), and includes a central keyhole
4 156 having a non-circular cross section, and two end effector
5 channels 158 (only one shown) through which the end effector wires
6 22, 24 extend. The distal end 32 of the clip-advancing wire 30
7 can be longitudinally moved through the keyhole 156, with the
8 transition 159 of the clip-advancing wire 30 from non-circular to
9 circular outer shape functioning as a stop against the keyhole 156
10 for additional distal movement.

11
12 Referring to Fig. 2B, the distal end 32 of the clip-advancing
13 wire 30 also includes notches 250 along one side 251 of the distal
14 end 32 which have a distal surface 252 substantially perpendicular
15 to the side 251 and proximal beveled surface 254. The coil
16 connector 152 includes a resilient catch 256 in alignment with the
17 notches 250. When the clip-advancing wire 30 is moved distally
18 through the keyhole 156, the beveled surface 254 of the notches
19 250 rides against the catch 256, bending the catch for clearance.
20 However, as distal surface 252 interferes with the catch 256 when
21 the clip-advancing wire 30 is moved proximally relative to the
22 coil connector 152, the clip-advancing wire 30 may not be moved
23 proximally by a distance which would cause a notch 250 to pass the
24 catch 256 (Fig. 2C).

25

1 Moreover, rotation of the clip-advancing wire 30 causes a
2 rotational moment to be applied to the connector 152 and
3 consequently the distal end of the tubular coil 12. The distal
4 end of the preloaded tubular coil 12 can be thereby rotated 360°
5 in each of the clockwise and counterclockwise directions by
6 rotation of the rotation knob 62 attached to the proximal end of
7 the clip-advancing wire 30. Because the end effector assembly 13
8 is attached to the distal end of the tubular coil, rotation of
9 knob 62 effects rotation of the end effector assembly 13 and the
10 jaws 18, 20.

11
12 The end effector wires 22, 24 are large enough in diameter to
13 preferably handle up to fifteen pounds of closing force from the
14 handle assembly and also to handle the force required to open the
15 jaws 18, 20 without buckling. However, the end effector wires
16 must be small enough in diameter to attach to the jaws, and fit in
17 the tubular coil 12. A preferred diameter for the end effector
18 wires is approximately 0.178 mm to 0.375 mm (0.007 inch to 0.015
19 inch), though other sizes may be used.

20
21 Referring to Figs. 9 and 10, the clevis 14 of the end
22 effector assembly 13 is preferably coupled directly to the distal
23 end of the tubular coil 12. The clevis 14 includes a central clip
24 channel 164 having a preferably rectangular cross section, and two
25 lateral openings 165 through which the distal ends of the end

1 effector wires 26, 28 can respectively exit. The jaws 18, 20 are
2 each rotatably coupled about the clevis 14 with a respective axle
3 166 (one shown) which does not interfere with the channel 164.
4 Each jaw 18, 20 includes a proximal tang 168, 169 respectively,
5 which is coupled to the distal ends of the respective end effector
6 wires 26, 28. The distal portion of each jaw 18, 20 includes a
7 clip guide 170, 172, respectively, and clamping surfaces 174, 176
8 on jaw 18, and clamping surfaces 178, 180 on jaw 20 extending
9 along each side of the guide 172. All of the clamping surfaces
10 174, 176, 178, 180 preferably have proximally directed teeth 182
11 which pulls target tissue toward the clip channel 164 as the jaws
12 are closed, and also securely grips the tissue when a clip is
13 advanced thereover. The distal end of jaw 18 includes an anvil
14 184 which is in alignment with the clip guide 170 which curves (or
15 is angled) toward jaw 20. Jaw 20 includes two distal anvil guides
16 186, 188 between which the anvil 184 is positioned when the jaws
17 are moved to a closed position. Jaw 20 also defines a distal well
18 190 between the anvil guides 186, 188 which is lower than the
19 surface of clip guide 172.

20
21 Referring to Fig. 11, a clip chamber 200 for storing a
22 plurality of linearly arranged clips 202 (Fig. 2A), described
23 further below, is formed between the coil connector 152 (Figs. 2
24 and 2A) and the distal end 16 of the tubular coil 12. The clip
25 chamber 200 extends into the clip channel 164 of the clevis 14.

1 The clip pusher 34 is provided at the proximal end of the chamber
2 and situated to push on a proximalmost clip such that all clips in
3 front of the clip pusher 34 are advanced toward the jaws 18, 20
4 when the clip-advancing lever 52 is actuated to cause the clip-
5 advancing wire 30 to move distally relative to the tubular coil
6 12.

7
8 The clip pusher 34, preferably made of stainless steel, is
9 coupled to the distal end 32 of the clip-advancing wire 30, e.g.,
10 by mechanical joining or welding. The clip pusher 34, as
11 described in more detail below, is provided with a shape
12 substantially similar to the distal portion of a clip 202 (Fig.
13 2A) adapted to be used in the clip applier. Such clips 202 are
14 described in detail in previously incorporated U.S. Serial No.
15 09/891,775. Generally, referring to Fig. 2A, the clips 202 are
16 each in a generally U-shaped configuration with first and second
17 arms 204, 206, and a bridge portion 208 therebetween. The first
18 arm 204 extends into a deformable retainer 214 preferably having a
19 tissue-piercing end 216 and preferably also a hook 218, and the
20 second arm 206 is provided with a tip 210 preferably having one or
21 more catches 212. The clip 202 is provided with structure that
22 facilitates the stacking (or chaining) of a plurality of clips in
23 the clip chamber 200. The structure includes: a notch 220 at a
24 junction of the second arm 206 and the bridge portion 208 which is
25 adapted to receive the tip 210 of the second arm 206 of another

1 clip; an elongate recess 222 along the exterior of the first arm
2 204 which is adapted to receive the retainer 214 of the first arm
3 of another clip; and an interior configuration 224 at the ends of
4 the first and second arms which corresponds to an exterior shape
5 of the proximal bridge portion 208 of another clip. In one
6 embodiment, the clips 202 are each approximately 6.86 mm (0.27
7 inch) in length from the bridge 208 to the end of the retainer
8 214, have a width of approximately 0.90 mm (0.035 inch), and a
9 height of 1.80 mm (0.070 inch). However, it is understood that
10 the clip dimensions may be adapted for use in devices having
11 tubular coil inner diameters of various sizes.

12
13 Referring to Figs. 2 and 2A, the clip pusher 34 includes a
14 rear clip seat 228 which corresponds to the exterior shape of the
15 proximal end of the clip. The clip pusher 34 also includes a
16 distally extending arm 230 having a distal clip catch 232 (adapted
17 to seat in the recess 222 of clip 202), and a shoulder 234
18 adjacent the clip seat 228 on the side opposite the arm 230. As
19 such, the clip pusher 34 includes structure which is adapted to
20 conform the proximal end of a clip 202 for transferring a pushing
21 force relative to the tubular coil. In addition, the clip catch
22 232, by engaging in the recess 222 of a clip 202, prevents clips
23 from unintentionally moving distally. The clip catch also permits
24 moving a clip 202 proximally, by retracting the clip pusher 34
25 such that the clip catch 232 forces back against wall at the rear

1 of the recess 222 and pulls the engaged clip proximally, which in
2 turn moves other clips in the 'chain'. The operation of the
3 distal portion of the device 10 (including the end effector
4 assembly 13, the clip pusher 34, and the clip chamber 200) will
5 become evident with reference to the following description of the
6 use of the device 10.

7
8 Referring to Figs. 4 and 12, the jaw closing lever 48 is
9 moved toward the stationary handle 46, against the bias of spring
10 56, to cause the jaws 18, 20 of the end effector 13 to move into a
11 closed position. Movement of the lever 48 adapts, in size, the
12 distal end of the device for delivery through the lumen (working
13 channel) of an endoscope, but preferably does not substantially
14 load the end effector wires 22, 24. Once the end effector
15 assembly 13 has exited the distal end of the endoscope, the jaw
16 closing lever 48 can be released to open the jaws (Fig. 1).

17 Referring now to Fig. 13, the proximal rotation knob 62 can be
18 rotated which, as discussed above, effects rotation of the entire
19 clip-advancing wire 30 and, hence, rotation of the end effector
20 assembly 13. Briefly, this is because the end effector assembly
21 13 is coupled to the tubular coil 12 and the tubular coil is
22 provided with a fixed coil connector 152 which is rotated by
23 rotation of the distal end 32 of the clip-advancing wire 30.

24

1 Turning now to Fig. 14, once the jaws 18, 20 of the end
2 effector assembly 13 are positioned on either side of tissue (not
3 shown) about which it is desired to place a clip 202 (Figs. 2 and
4 2A), the jaw closing lever 48 is again moved toward the stationary
5 handle 46 to clamp the jaws about the tissue. The lever 48 is
6 moved relatively further than shown in Fig. 12, as the wires 22,
7 24 will be under load to compress the tissue. Referring back to
8 Figs. 9 and 10, the teeth 182 on the clamping surfaces 174, 176,
9 178, 180 of the jaws 18, 20 are angled proximally to pull the
10 tissue into the jaws assembly and securely hold the tissue against
11 the distally directed force of an advanced clip. As the jaws
12 close, the anvil 184 moves between the anvil guides 186, 188, and
13 may partially or fully pierce the tissue.

14
15 Once the jaws are fully clamped about the tissue, the locking
16 tooth 90 engages with the lever lock 110 as the latch 94 moves
17 down to allow engagement and thereby lock the jaw closing lever 48
18 relative to the stationary handle 46, as discussed above with
19 respect to Figs. 6 and 7. As discussed above, the jaws are locked
20 based upon the load in the handle, rather than at any particular
21 position. This permits locking the jaws about tissues of various
22 thicknesses and compressive properties. Moreover, it is noted
23 that when the jaws 18, 20 are fully clamped, the end effector
24 wires 22, 24 are placed under tension which provides compression

1 to the tubular coil 12 such that the coil has an effectively
2 higher tensile limitation before stretching.

3
4 Referring now to Figs. 15 and 16, after the jaws are clamped
5 about the tissue, the clip-advancing lever 52 is rotated about the
6 pivot pin 54 to effect advancement of the clip-advancing wire 30
7 through the tubular coil 12. More particularly, as lever 52 is
8 rotated toward the jaw closing lever 48, the pinion 70 engages the
9 rack 68 to move the rack relatively distally. As the proximal end
10 of the clip-advancing wire 30 is longitudinally fixed relative to
11 the rack 68, the distal end 32 of the clip-advancing wire 30 is
12 consequently moved distally. Referring to Figs. 10 and 17, the
13 pusher 34, at the distal end 32 of the clip-advancing wire 30
14 distally advances the clips 202a, 202b, 202c, 202d in the chamber
15 200, and particularly forces the distalmost clip 202a through the
16 channel 164 in the clevis 14 and between the jaws 18, 20. As clip
17 202a is further advanced, the first and second arms 204, 206 ride
18 in guides 170, 172, respectively, and are forced over the tissue
19 held between the jaws 18, 20. When the retainer 214 on the first
20 arm 204 of the clip 202a is forced against the anvil 184, the
21 retainer 214 is bent toward jaw 20; the tip 216 pierces the tissue
22 between the jaws 18, 20 (or is guided into the pierce hole made by
23 the anvil 184 when the jaws clamped the tissue); and the tip 216
24 enters the well 190 at the distal end of jaw 20 to extends around
25 the tip 210 of the second arm 206 which overhangs the well. The

hook 218 at the tip 216 of the retainer 214 may engage (although it does not necessarily engage), the latch 212 at the distal end of the second arm 206. The force provided by the clip-advancing wire 30 to advance a clip 202 over the clamped tissue, to bend the retainer 214 against the anvil 184, and to force the tip 216 of the retainer to pierce tissue is at least 500 grams (1.1 lbs), and more typically approaches 1500 grams (3.3 lbs) or higher.

Referring now to Figs. 6 and 18, after the clip is applied, the jaws 18, 20 are released from about the tissue. This is done by pressing the release button 124 of the lever lock 110 such that the jaw closing lever 48 is permitted to move relative to the stationary handle 46.

Referring to Fig. 19, the clip is then released from the end effector jaw assembly by moving the jaw assembly relative to the applied clip 202a. The end effector assembly may then be moved to another tissue location to apply additional clips.

It is noted that after clip 202a is released, the retainer 214b of clip 202b partially extends into the space between the jaws 18, 20. If not retracted, this retainer 214b would obstruct positioning the jaws 18, 20 about the tissue and subsequent clip application during the procedure. However, when the clip-advancing lever 52 is released, torsion spring 58 (Fig. 4)

1 operates to pull back the clip-advancing wire 30 and the clip
2 pusher 34 and thereby retract the 'chain' of clips. That is, the
3 clip catch 232 of the clip pusher pulls back on clip 202d, and the
4 retainer 214d of clip 202d pulls back clip 202c, and so on, until
5 the extending retainer 214b is pulled within the chamber 164 of
6 the clevis, and the space between the jaws 18, 20 is cleared, as
7 shown in Figs. 20 and 21. The clip-advancing wire is limited in
8 the distance by which it can be retracted; it may be retracted
9 only so far as permitted by interference of a ridge 250 on the
10 clip-advancing wire 30 located just distal the catch 256 of the
11 coil connector 152, and the catch 256 (Fig. 2B), which is
12 constructed to be approximately the length of the protruding
13 retainer 214b.

14
15 The device may then be used to apply another clip, or the
16 jaws may be closed and the device may be withdrawn through the
17 endoscope.

18
19 The resulting clip applier is capable of transmitting a
20 pushing force at the distal end of the clip-advancing wire,
21 resulting from the compressive force applicable to the clip-
22 advancing wire and the relative tensile force applicable to the
23 outer tubular coil and end effector wires, far in excess of the
24 perceived threshold of the 200 grams (0.44 lbs) in the prior art.
25 In fact, as discussed below, one embodiment of the device of the

1 invention provides a pushing force in excess of 2267 grams (5
2 lbs).

3
4 More particularly, referring to Fig. 22, a table listing part
5 dimensions of six prototype device, and the resultant output
6 forces achieved with prototype devices is provided. Fig. 23
7 provides an efficiency plot (input pushing force v. output pushing
8 force) for the use of the prototypes. In all prototypes, the
9 tubular coil, clip-advancing wire, and end effector wires are made
10 from stainless steel. Details of the table and the efficiency
11 plot are discussed below with respect to Examples 1 through 6.

12
13 EXAMPLE 1

14 In a first prototype, indicated by 'RUN #1', 'RUN #2' and
15 'RUN #3', the tubular coil 12 has an outer diameter of 0.09 inch
16 and an inner diameter of 0.06 inch. The clip-advancing wire 30
17 has an outer diameter of 0.017 inch and the end effector wires 22,
18 24 each have an outer diameter of 0.011 inch. The proximal end of
19 the end effector wires 22, 24 are pulled with 11 lbs of force
20 which generally results in 5 to 10 lbs of force at the distal end
21 of the end effector wires, depending on the degree to which the
22 tubular coil 12 is bent (modeled by looping the tubular coil
23 through two inch loops); i.e., frictional losses reduce the
24 transmitted force. Moreover, it is noted that whatever force is
25 transmitted to the distal end of the end effector wires 22, 24,

1 only approximately one-fifth of that force is applied to the jaws,
2 as the distance from the jaw tang 168 to the pivot 166 is
3 relatively shorter than the length of the end of the jaw (anvil
4 184) to the pivot 166, approximately in a one to five ratio. As
5 such, an input force of 11 lbs may results in one to two lbs of
6 force on the jaws 18, 20. Applying the pulling force simulates
7 the in-use condition in which the pushing force is transmitted.

8
9 With the tubular coil 12 extending relatively straight (i.e.,
10 through no loops) in 'RUN #1', an input pushing force of 8 lbs on
11 the proximal end of the clip-advancing wire 30 (i.e., a pushing
12 force of 8 lbs on the rack 68) resulted in an output pushing force
13 of 3.82 lbs (1732.7 grams) at the clip pusher 34 at the distal end
14 32 of the clip-advancing wire 30. With the tubular coil 12
15 extending through one two-inch loop in 'RUN #2', an input pushing
16 force of 8 lbs resulted in an output pushing force of 3.42 lbs
17 (1551.3 grams). With the tubular coil 12 extending through two
18 two-inch loops, in 'RUN #3', an input pushing force of 7 lbs
19 resulted in an output pushing force of 3.37 lbs (1528.6 grams).

20
21 EXAMPLE 2

22 In a second prototype, indicated by 'RUN #4', the diameters
23 of the tubular coil 12 and end effector wires 22, 24 are the same
24 as Example 1. However, the diameter of the clip-advancing wire 30
25 is decreased to 0.015 inch. With the tubular coil 12 extending

1 through no loops, a six pound input pushing force resulted in an
2 output pushing force of 2.11 lbs (957 grams).

3

4 EXAMPLE 3

5 In a third prototype, indicated by 'RUN #5', 'RUN #6' and
6 'RUN #7', the diameters of the tubular coil 12 and end effector
7 wires 22, 24 are the same as Example 1. However, the diameter of
8 the clip-advancing wire 30 is increased to 0.02 inch. With the
9 tubular coil 12 extending through no loops in 'RUN #5', an input
10 pushing force of 8 lbs resulted in an output pushing force of 4.03
11 lbs (1828 grams). With the tubular coil 12 extending through one
12 two-inch loop in 'RUN #6', an input pushing force of 8 lbs
13 resulted in an output pushing force of 4.08 lbs (1851 grams).
14 With the tubular coil extending through two two-inch loops, in
15 'RUN #7', an input pushing force of 8 lbs resulted in an output
16 pushing force of 3.54 lbs (1605.7 grams).

17

18 EXAMPLE 4

19 In a fourth prototype, indicated by 'RUN #8' and 'RUN #9',
20 the device includes a tubular coil 12 having an outer diameter of
21 0.086 inch and an inner diameter of .053 inch, a clip-advancing
22 wire 30 having a diameter of 0.017 inch, and end effector wires
23 22, 24 having diameters of 0.009 inch. With the tubular coil
24 extending through no loops, an input pushing force of 8 lbs
25 resulted in 4.61 lbs (2091 grams) of output pushing force. With

1 the tubular coil extending through two two-inch loops, an input
2 pushing force of 8 lbs resulted in 4.28 lbs (1941.3 grams) of
3 output pushing force.

4

5 EXAMPLE 5

6 In a fifth prototype, indicated by 'RUN #10', the clip-
7 advancing wire 30 and end effector wires 22, 24 of the device 10
8 have the same diameters as Example 4. The tubular coil 12 has an
9 outer diameter of 0.086 inch and an inner diameter of 0.054 inch.
10 With the tubular coil 12 extending through no loops, an input
11 pushing force of 8 lbs resulted in 4.42 lbs (2004.9 grams) of
12 output pushing force.

13

14 EXAMPLE 6

15 In a sixth prototype, indicated by 'RUN #11', the clip-
16 advancing wire 30 and end effector wires 22, 24 of the device 10
17 have the same diameters as Example 4. The tubular coil 12 has an
18 outer diameter of 0.083 inch and an inner diameter of 0.054 inch.
19 With the tubular coil 12 extending through no loops, an input
20 pushing force of 8 lbs resulted in 5.17 lbs (2345 grams) of output
21 pushing force.

22

23 Other flexible clip applicers suitable for use through a
24 relatively smaller 2.6 mm diameter endoscope have also been
25 constructed and tested. For example, one clip applicer has a

1 tubular coil 12 with an outer diameter of 0.092 inch, and an inner
2 diameter of 0.060 inch, a clip-advancing wire 30 with a diameter
3 of 0.022 inch, and end effector wires 22, 24 each with a diameter
4 of 0.013 inch. The device can apply a pushing force of between 3
5 lbs (1361 grams) and 5 lbs (2268 grams) depending on the number of
6 two-inch loops through which the tubular coil was wound.

7

8 It is therefore appreciated that other dimensions may be used
9 for devices intended for use in endoscopes having working channels
10 of other sizes. Moreover, the device may be used outside an
11 endoscope, where it is not limited by the size of the working
12 channel.

13

14 From the foregoing examples, it will be appreciated that a
15 flexible surgical clip applier, suitable for use through an
16 endoscope is hereby provided. The device is capable of effecting
17 a pushing force far in excess of the previously considered
18 limitation of approximately 200 grams for a mechanical system
19 sized to be used through an endoscope. See C. Paul Swain, "What
20 Endoscopic Accessories Do We Really Need?", *Emerging Technologies*
21 *in Gastrointestinal Endoscopy, Gastrointest. Endosc.*, Vol. 7, No.
22 2, pp. 313-330 (April 1997), discussed above. This substantial
23 force permits clips to be forced over tissue and thereby makes
24 available clip clamping, closure, and 'suturing' in an endoscopic
25 procedure.

1 There have been described and illustrated herein embodiments
2 of a flexible surgical clip applier. While particular embodiments
3 of the invention have been described, it is not intended that the
4 invention be limited thereto, as it is intended that the invention
5 be as broad in scope as the art will allow and that the
6 specification be read likewise. Thus, while particular materials
7 have been disclosed, it will be appreciated that other materials
8 can be used as well. In addition, while particular dimensions
9 have been disclosed, it will be understood that other suitable
10 dimensions can be used as well. Also, while the device has
11 particularly been described for use in endoscopic procedures,
12 where a great need exists for such a device, it will be
13 appreciated that flexible, non-endoscopic devices are considered
14 within the scope of the invention. For example, the tubular coil
15 may have a substantially shorter length and the device may be used
16 through body orifices such as the ear canal, the nasal passages,
17 and through the larynx and trachea. By way of another example,
18 elements of the device may have substantially larger dimensions
19 and the device can be used through a trocar port. Furthermore,
20 while both jaws are shown rotatable about a clevis, it will be
21 appreciated that only one jaw need be rotatable relative to the
22 other. Also, while two clip guides, one on each jaw, are shown,
23 it is recognized that only a single clip guide on one of the jaws
24 is required. Moreover, while the device of the invention is
25 described as having two end effector wires, it will be appreciated

1 that a single control wire may be used which is coupled to at
2 least one of the jaws, and the other jaw may be stationary or
3 mechanically linked to also close and open upon actuation of the
4 single end effector wire. Also, while the device has been
5 described with respect to a clip-advancing wire and end effector
6 wires, it will be appreciated that reference to the 'wires' is
7 intended to also include non-metal filaments, multifilamentary
8 constructs, such as cables, and coils. In addition, while the end
9 effector wires when subject to a tensile force create a
10 compressive force on the tubular coil which effectively increases
11 its tensile capability to facilitate pushing a clip over clamped
12 tissue without exceeding the tensile limitation of the coil, it is
13 recognized that other mechanisms may be used to increase the
14 tensile limitation of the coil. For example, a preferably flat
15 and preferably wire ribbon may be coupled to the inside the coil
16 to limit the amount by which the coil can be stretched.

17 Furthermore, while the ability to provide a relative high pushing
18 force at the distal end of a clip-advancing wire is disclosed with
19 respect to a clip applier, it is recognized that such capability
20 has application to instruments other than clip appliers; for
21 example, for endoscopic staplers, lithotriptors, or any other
22 instrument where it is desired to hold tissue and apply a pushing
23 force, such as a device for tagging. It will therefore be
24 appreciated by those skilled in the art that yet other

- 1 modifications could be made to the provided invention without
- 2 deviating from its spirit and scope as claimed.

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